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5. 510(k) Summary

In accordance with the requirements of the Safe Medical Device Act of 1990 and 21 CFR 807.92, ConMed Linvatec is hereby submitting the 510(k) Summary of Safety and Effectiveness for 510(k) Number K111779.

Date Prepared: July 25, 2011

A. Submitter

ConMed Linvatec
11311 Concept Boulevard
Largo, Florida 33773-4908
Registration Number: 1017294

B. Company Contact

Regulatory Contact:
John Cusack
Regulatory Affairs Manager
(727) 399-5562 Telephone
(727) 399-5264 Fax

C. Device Name

Trade Name:	Y-Knot™ All-Suture Anchor
Common Name:	Non-absorbable Suture Anchor System
Classification Name:	Fastener, Fixation, Nondegradable, Soft tissue
Proposed Class/Device:	Class II
Product Code:	MBI
Regulation:	21 CFR Part 888.3040

D. Predicate/Legally Marketed Devices

Device Name:	ConMed Linvatec Bio Mini Revo
Company Name:	ConMed Linvatec
510(k) #:	K053561
Device Name:	ConMed Linvatec Soft Tissue to Bone System
Company Name:	ConMed Linvatec
510(k) #:	K091549
Device Name:	Biomet JuggerKnot Soft Anchor
Company Name:	Biomet Sports Medicine
510(k) #:	K110145

E. Device Description

The ***Y-Knot™ All-Suture Anchor*** is a soft-tissue fixation device with an expandable push-in design, provided preloaded on a disposable inserter device. This suture anchor is constructed of a flat suture that is interlaced longitudinally along its central width by one suture strand. The flat suture and the single suture strand are folded back on themselves at the distal end of the disposable inserter. The disposable inserter device has a forked shaped distal end, stainless steel shaft, with an ABS handle, that is provided sterile, for single use and is removed at the end of the repair leaving behind an all suture construct. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The all-suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

The suture anchor configuration is supplied sterile, single use, preloaded onto a disposable driver. The disposable driver is composed of a 300 series surgical grade stainless-steel shaft with an ABS handle. Additional surgical instruments, including a drill bit and drill guides, are Class I, sterile, single-use devices intended for transient use during orthopedic procedures.

F. Testing

The verification and validation testing of the Y-Knot™ All-Suture Anchor includes fixation strength, pull-out, cyclic loading, insertion, biocompatibility, sterilization, shelf-life, packaging/transportation and side-by-side comparator qualifications.

G. Intended Use / Indications

The Y-Knot™ All-Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

H. Substantial Equivalence

The Y-Knot™ All-Suture Anchor is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the ConMed Linvatec Bio Mini Revo (K053561), the ConMed Linvatec Soft Tissue to Bone System (K091549) and the Biomet JuggerKnot Soft Anchor (K110145).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

ConMed Linvatec
% Mr. John Cusack
Regulatory Affairs Manager
11311 Concept Boulevard
Shelton, Connecticut 06484

AUG - 8 2011

Re: K111779
Trade/Device Name: Y-Knot™ All-Suture Anchor
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: MBI
Dated: July 26, 2011
Received: July 27, 2011

Dear Mr. Cusack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for DSP CDRH

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K 111779 (1/1)

6. Indications for Use

510(k) Number (if known): _____

Device Name: Y-Knot™ All-Suture Anchor

Indications for Use:

The Y-Knot™ All-Suture Anchor is intended to reattach soft tissue to bone in orthopedic surgical procedures. The system may be used in either arthroscopic or open surgical procedures. After the suture is anchored to the bone, it may be used to reattach soft tissue, such as ligaments, tendons, or joint capsules to the bone. The suture anchor system thereby stabilizes the damaged soft tissue, in conjunction with appropriate postoperative immobilization, throughout the healing period.

Prescription Use ____X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off) for M. Mellerson
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111779